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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,232	05/02/2001	Ning Huang	0665-0018.30	5945
22918	7590	10/08/2003		
PERKINS COIE LLP				
P.O. BOX 2168				
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			EXAMINER	
			BAUM, STUART F	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/847,232

### Applicant(s)

HUANG ET AL.

### Examiner

Stuart F. Baum

### Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18,23 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 May 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. The amendment filed 7/23/2003 has been entered.  
  
Claims 18, and 23-24 are pending.  
  
Claims 1-17 and 19-22 have been canceled.  
  
Claims 23-24 have been newly added.
2. Claims 18 and 23-24 are examined in the present office action.
3. Rejections and objections not set forth below are withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

***Written Description***

5. Claim 18 remains rejected and claims 23-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 1/19/2003. Applicant's arguments filed 7/30/2003 have been fully considered but they are not persuasive.

Applicants contend the specification teaches preparing a heterologous construct containing the native Gt1 promoter modified to contain a 98 bp Reb UAS fragment.

Applicants' traversal is not persuasive because Applicants are arguing limitations not present in the claims. The claims are not limited to any particular sequence, rather, they are

drawn to any Reb transcription factor and any native responsive sequence for any Reb transcription factor. In addition, Applicants have not disclosed the 98 bp sequence or how one isolates the sequence from a Glb promoter.

### *Scope of Enablement*

6. Claim 18 remains rejected and claims 23-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a rice glutelin 1 (Gt1) promoter operably linked to a reporter gene coding sequence in which the 98 bp *Oryza sativa* bZIP (Reb) upstream activation sequence (UAS) fragment containing three copies of GCCACGT(C/A)AG was inserted at position -630 bp distal to the TATA box of the Gt1 promoter co-transformed into rice endosperm with a Reb coding sequence and promoter to increase expression of the GUS gene when compared to GUS expression in endosperm cells only transformed with the UAS-Gt1::GUS construct, does not reasonably provide enablement for claims broadly drawn to a method of making a modified Gt-1 seed-specific promoter responsive to any Reb transcription factor comprising a native Gt1 seed-specific promoter and inserting any Reb response sequence into said native Gt1 seed-specific promoter at any location. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 1/19/2003. Applicant's arguments filed 7/30/2003 have been fully considered but they are not persuasive.

Applicants contend that Example 2 provides guidance for an exemplary method of preparation and testing of a modified Gt1 seed-specific promoter responsive to a Reb transcription factor (page 3 of Remarks, 2<sup>nd</sup> paragraph).

The Office contends that Applicant is enabled for the modified Gt1 promoter comprising UAS sequence exemplified in the specification (page 30 line 34 through page 31, line 36). Applicant is not enabled for a method of making any modified Gt1 seed specific promoter responsive to any Reb transcription factor from any plant. As discussed in the previous office action, the binding of transcription factors to the correct cis-acting element requires the coordinated binding of other proteins that together make up the transcriptional machinery of which Applicant's Reb transcription factor is a part. Applicants have not taught the other UAS elements that any Reb transcription factor will bind. In addition, on page 31, line 3-12 as referenced in Applicants' remarks (3<sup>rd</sup> paragraph of "Enablement" remarks), Applicants only teach the location of a 200 bp fragment from the Glb promoter, and not the 98 bp fragment the Applicants used to increase transcription. Applicants specify a 98 bp fragment, but then mention that this 98 bp fragment was used to generate the Gt1+UAS-GUS of Fig 8A (page 31 lines 13-25), but Fig 8A specifies a 200 bp fragment. Before one can test the expression of a construct, one must be able to make constructs that are operable. Promoters are very sensitive to random insertions, single base insertions can ablate promoter function. Given the lack of guidance or examples and given the state-of-the-art as disclosed in the previous office action, it would require undue experimentation for one skilled in the art to make and/or use the broadly claimed invention.

7. No claims are allowed.
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 703-305-6997. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Stuart F. Baum Ph.D.

October 3, 2003

Handwritten signature of Phuong T. Bui, dated 10/6/03.

PHUONG T. BUI  
PRIMARY EXAMINER